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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,954	07/12/2001	Michael E. Garst	17095CIPCON(AP)	3028

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ALLERGAN, INC.
Carlos A. Fisher-T2-7H
2525 Dupont Drive
Irvine, CA 92612

EXAMINER	
FAY, ZOHREH A	
ART UNIT	**PAPER NUMBER**
1614	10

DATE MAILED: 11/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,954	GARST, MICHAEL E.	
	Examiner	Art Unit	
	Zohreh Fay	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 14-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 14-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-7 and 14-27 are presented for examination.

Claims 21-27 are rejected under 35 U.S.C. 112 first paragraph for the reasons set forth on pages 2 and 3 of the office action of February 20, 2003.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 7 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,294,563. This is a double patenting rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 14-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gluckhowski (5,091,528) and Bishop et al. (5,510,3980).

Gluckhowski teaches the use of brimonidine for the treatment of glaucoma. See column 1, lines 1-6. The above reference differs from the claimed invention in the presence of a prostaglandin. Bishop et al. teach the use of the claim-designated prostaglandins for the treatment of glaucoma. See the abstract, column 1, formula 2

and 3, and column 2 lines 41-55. It would have been obvious for a person skilled in the art to incorporate a prostaglandin into the composition of the primary reference, considering that bishop et al. teach the use of the claim designated prostaglandins for the treatment of glaucoma as old and well known.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of brimonidine in a pharmaceutical formulation for the treatment of glaucoma, and the other relates to the use of the claimed prostaglandins for the treatment of glaucoma. It is generally considered prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two conventional anti-glaucoma agents. It would follow that the recited claims define prima facie obvious subject matter. See In re kerkhoven, 626, F.2d 848, 205 U.S.P.Q 1069 (CCPA 1980). Applicant alleges criticality to the neuroprotective effect of the claimed combination to the ocular nerves by lowering the intraocular pressure associated with glaucoma. The allegation is not well taken. It does not appear that the claim language or limitation result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Mayers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent

properties in the prior art does not render non-obvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on a discovery of an unknown but inherent function would remove from the public that which is the public domain by virtue of its inclusion in, or obviousness from, the prior art. In Re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed.Cir. 19910. See M.P.E.P. 2145. The use of the claimed combination for the treatment of glaucoma would inherently prevent and protect the ocular nerves. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-6 and 14-27 are properly rejected under 35 U.S.C. 103.

Applicant's arguments and remarks regarding the 112 first paragraph rejection have been carefully considered, but are not deemed to be persuasive. The instant specification fails to provide support for "preventing" the degeneration of optic nerve and providing "protection" of the retinal ganglion cells. The state of the art does not recognize that the prevention of neuronal damage is done easily. The instant specification fails to provide guidance to a person skilled in the art to determine how the prevention and protection of neuronal cells is accomplished.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F